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Filed : July 7, 2003

## REMARKS

### Interview Summary

Applicants thank the Examiner for the helpful comments provided during the telephonic discussion with the undersigned on April 10, 2007, and for the courtesy extended during the personal interview held on June 21, 2007 and the helpful comments made therein. During the personal interview between the undersigned, Marc Hedrick, Richa Nand and Examiner Lankford, the indefiniteness rejections under 35 U.S.C. § 112, second paragraph raised in the Office Action mailed January 29, 2007 were discussed. The undersigned and Examiner Lankford agreed that a claim directed to: A self contained adipose-derived stem cell processing unit, comprising a tissue collection container configured to receive unprocessed adipose tissue that is removed from a patient, wherein said tissue collection chamber is defined by a closed system; a first filter that is disposed within said tissue collection container, wherein said first filter is configured to retain a first component of said unprocessed adipose tissue and pass a second component of said unprocessed adipose tissue, such that said first filter separates said first component from said second component, and wherein said first component comprises a cell population that comprises adipose-derived stem cells and said second component comprises lipid, blood, mature adipocytes and saline; a cell collection chamber, which is configured to receive said first component comprising a cell population that comprises adipose-derived stem cells from said tissue collection container, wherein said cell collection container is within said closed system; a conduit configured to allow passage of said first component comprising a cell population comprising adipose-derived stem cells from said tissue collection chamber to said cell collection chamber while maintaining a closed system; a cell concentrator disposed within said cell collection chamber, which is configured to facilitate the concentration of said first component comprising a cell population that comprises adipose-derived stem cells, wherein said cell concentrator comprises a centrifuge or a spinning membrane filter; and an outlet configured to allow the aseptic removal of said concentrated population of cells that comprise adipose-derived stem cells, would likely overcome the rejections set forth in the Office Action dated January 29, 2007.

Pursuant to the conversation at the interview, Applicants provide herewith Table 1, showing a list related co-pending applications. As indicated in the Information Disclosure Statement, Applicants kindly request consideration of the Office Actions in the related cases. As

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discussed during the interview, Applicants will not provide the Examiner with paper copies of Office Actions issued in the co-pending cases listed below, and understand that the Examiner will review these documents online. Applicants wish to draw to the Examiner's attention to the fact that U.S. Application No.'s: 10/242094 and 10/035,278 are docketed to different Examiners. The remainder of the co-pending applications are docketed to Examiner Lankford.

**TABLE 1**

<b>Application No.</b>	<b>Attorney Docket</b>	<b>Examiner</b>	<b>Title or Claims</b>
11/584202	CYTH.002C1	Lankford	Self Contained Cell Processing Device/Methods of Use
10/783957	CYTH..002CP1	Lankford	Treatment of Cardiovascular Conditions
10/884861	CYTH.002CP10	Lankford	Treatment of Stroke and Related Disorders
10/884638	CYTH.002CP11	Lankford	Clinically Safe Adipose-Derived Regenerative Cells/Devices with Sensors
10/877822	CYTH.002CP2	Lankford	Device With Programmable Unit/Cell Culturing Chamber
10/871503	CYTH.002CP3	Lankford	Augmentation of Autologous Fat Transfer
10/885293	CYTH.002CP4	Lankford	Cell Carrier and Containment Devices Containing Adipose-Derived Stem Cells
10/884637	CYTH.002CP5	Lankford	Treatment of Musculoskeletal Disorders
10/884639	CYTH.002CP6	Lankford	Treatment of Renal Disorders and Diseases
10/885294	CYTH.002CP7	Lankford	Treatment of Inherited and Acquired Disorders of the Bone, Bone Marrow, Liver, and Other Tissues
10/884860	CYTH.002CP8	Lankford	Wound Healing
10/884871	CYTH.002CP9	Lankford	Treatment of Peripheral Vascular Disease and Related Disorders
10/614431	CYTH.002DV1	Lankford	Additive + Mixing Concentrated Populations of Cells with Adipose Tissue
10/614392	CYTH.002DV2	Lankford	Cooling Concentrated Cells Prior to Administration
10/614644	CYTH.002DV3	Lankford	Self-Contained Cell Processing Device with Filter and Cell Concentrator
10/614648	CYTH.002DV4	Lankford	Compositions of Unprocessed Adipose Tissue and Concentrated Adipose-Derived Stem Cells
10/614643	CYTH.002DV5	Lankford	Mixing Concentrated Adipose-Derived Stem Cells with Unprocessed Adipose Tissue
10/242094	CYTH.017A	Afremova	Preservation of Non-Embryonic Stem Cells from Non-Hematopoietic Tissues (Cryopreservation/Banking)
10/325728	CYTH.019A	Mohamed	Systems and Methods for Treating Patients With Collagen Rich Material Extracted from Adipose Tissue
11/317422	CYTH.2CP1CP	Lankford	Cell Loaded Prosthesis for Regenerative Intraluminal Applications
11/138083	CYTH.2CPCPCP	Lankford	Treatment of Cardiovascular Conditions

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Further to the discussion at the interview, the Information Disclosure Statement lists the following six references to be considered by the Examiner. The six references listed below have been submitted in related applications, and copies are provided herewith:

1. EP 0 418 979; Published March 27, 1991; Applicant Dr. Michele Zocchi
2. EP 0 448 770; Published October 2, 1991; Applicant Katsuya Takasu
3. EP 0 515 726; Published December 2, 1992; Applicant Katsuya Takasu
4. US 4,834,703; Date of Patent May 30, 1989; Dubrul, et al.
5. Fulton, et al. "Fat Grafting." Fundamentals of Cosmetic Surgery. Fulton Skin Institute, Tustin, California. 19(3): 523-530 (July 2001).
6. Nguyen, et al. "Comparative Study of Survival of Autologous Adipose Tissue Taken and Transplanted by Different Techniques." Study of Transplanted Adipose Tissue. Plastic and Reconstructive Surgery. 85(3): 378-386 (March 1999).

Applicants thank the Examiner for consideration of the enclosed references.

Response to Final Office Action

Claims 93-119 are pending in the instant application and stand rejected by the Examiner. Applicants have amended Claims 93-119. The amendments to the claims add no new matter and are fully supported by the specification and claims as originally filed. In particular, support for the amendment to Claim 93 specifying that the filter within the tissue collection container separates a cell population comprising adipose-derived stem cells from lipid, blood and saline can be found, for example, on page 5, line 30 -page 6 line 2; page 13, lines 1-10; and page 26, lines 10-13. Support for the amendment to Claim 93 specifying that that the cell collection container is configured to receive adipose-derived stem cells from the tissue collection chamber can be found, for example, on page 14, lines 1-9. Support for the amendment to Claim 93 specifying the conduit that connects the tissue collection chamber and the cell collection chamber while maintaining a closed system can be found, for example, on page 14, lines 1-7 and page 31, lines 27-29. Support for the amendment to Claim 93 specifying that the cell collection chamber contains a cell concentrator, *i.e.*, a centrifuge or a spinning membrane filter can be found, for example, page 14, lines 28-31 and on page 27, lines 16-18. Support for the amendment to Claim 116 specifying that a conduit configured to maintain a closed system connects the mixing

chamber and the tissue collection chamber can be found, for example, in Figure 1 and on page 28, ones 21-28.

Applicants respond below to the specific rejections raised by the Examiner in the Office Action.

**Rejections Under 35 U.S.C. § 112, first paragraph**

The Examiner states that the claims fail to particularly point out and distinctly claim the invention. Specifically, the Examiner alleges that the claims omit essential structural cooperative relationships of elements, such as between the filter, the tissue collection chamber, and the cell collection chamber. The Examiner further states that the claims do not recite an element to facilitate the concentration and/or separation of the stem cells from adipose tissue, as recited in the claims. Next, the Examiner states that the claims are unclear because the apparatus has a means for separating adipose tissue from lipid, blood and saline, but also refers to the collected tissue as "adipose tissue." Finally, the Examiner states that the claims do not detail how the apparatus facilitates the transition between adipose tissue and adipose-derived stem cells.

Applicants have amended the claims to recite that the filter (*i.e.*, first filter) is disposed within said tissue collection chamber. Further, Applicants have specified that a conduit connects the tissue collection chamber and the cell collection chamber, so as to maintain a closed pathway. Applicants maintain that the amendments clarify the structural cooperative relationship between the filter, the tissue collection chamber, and the cell collection chamber. Accordingly, Applicants respectfully submit that the amendments address and overcome the Examiner's rejections as they relate to the cooperative relationship between the recited elements.

Further, Applicants have specified that the tissue collection chamber comprises a filter to separate a cell population comprising adipose-derived stem cells from lipid, blood, and mature adipocytes. Applicants have also specified that cell collection chamber comprises a cell concentrator that includes a centrifuge or a spinning membrane filter to separate/concentrate the adipose derived stem cells. As such, Applicants respectfully submit that the present amendments address and overcome the Examiner's rejections as they relate to the need for an element to facilitate the concentration and/or separation of the stem cells from adipose tissue.

Applicants also respectfully submit that the claims, as amended, particularly point out how the adipose tissue is transitioned from a crude state into a concentrated population of

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adipose-derived stem cells. In particular, the claims specify that the filter disposed within the tissue collection chamber retains a first component of the unprocessed adipose tissue comprising a population of cells comprising adipose-derived stem cells and passes a second component of the unprocessed adipose tissue comprising blood and mature adipocytes. The first component then enters into the cell collection chamber via a conduit wherein it is concentrated so as to yield a concentrated population of adipose-derived stem cells in the cell concentrator within the cell collection chamber. As set forth above, the claims precisely point out the transition between the unprocessed adipose tissue and the concentrated population of adipose-derived stem cells.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

#### CONCLUSION

In view of the above amendments and remarks, Applicants respectfully maintain that the claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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